

Appl. No. 09/940,471  
Amdt. dated October 14, 2004  
Reply to Office Action of July 14, 2004

### REMARKS

Applicants have received and carefully reviewed the Office Action mailed July 14, 2004. Claims 192-206 and 208-217 remain pending, with claims 191 and 207 cancelled herein without prejudice. Reconsideration and reexamination are respectfully requested.

In paragraph 3 of the Office Action, claims 191-194 and 196-200 were rejected under 35 U.S.C. §112, second paragraph as being indefinite due to a lack of antecedent basis in claim 191 for the phrase "the step of sensing an abnormality". Claim 191 has been cancelled without prejudice, obviating that portion of the rejection. Claim 193 has been amended to incorporate base claim 191. Claim 193 already set forth a step of sensing an abnormality, and therefore, the amendment remedies the identified lack of clarity with respect to claim 193. Claims 192 and 200 have been amended to depend from claim 193, and claims 194 and 196-199 already depended from claim 193. It is believed that these amendments have overcome the rejections.

In paragraph 5 of the Office Action, claims 191-192 were rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 5,411,547 to Causey, III. The rejection of claim 191 has been obviated due to its cancellation without prejudice. Claim 192 has been amended to depend from claim 193. As claim 193 is believed to be in condition for allowance, as further discussed below, claim 192 is also believed to be allowable.

In paragraph 6 of the Office Action, claims 207, 210 and 215 were rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 5,230,337 to Dahl et al. Claim 207 has been cancelled, obviating that portion of the rejection. Claim 211, which was noted by the Examiner as being objected to but containing allowable subject matter, has been amended to incorporate the recited elements of former claim 207, and therefore is believed to be in condition for allowance. Claims 210 and 215 have been amended to depend from claim 211, such that the objection is believed overcome. In light of these amendments, it is believed these rejections should be withdrawn.

In paragraph 8 of the Office Action, claims 193-194 and 196-199 were rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 5,411,547 to Causey, III in view of U.S. Patent No. 5,476,503 to Yang. After careful review of the cited references, Applicants respectfully disagree.

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The proposed rejection suggests modification of Causey, III by the inclusion of electrodes as suggested by Yang. However, there are a number of difficulties with this combination.

First, as noted by the Examiner, Causey, III does not suggest sensing an abnormality using electrodes disposed internally to the patient but not contacting the patient's heart. In particular, Causey, III suggests modifications to stimulation electrodes, but "[t]he sensor is typically located in a transvenous pacing lead." (Causey, III, at column 1, lines 34-35). Such leads are positioned within the heart, as taught by Causey, III. (Column 1, lines 41-44). Thus, Causey, III does not suggest that sensing can be performed outside of the transvenous pacing lead. Yang presents a transvenous lead system in addition to a patch electrode placed on the heart. The patch electrode, therefore, contacts the patient's heart, and there is no suggestion in Yang for sensing an abnormality using electrodes disposed internally to the patient but not contacting the patient's heart. Hence the combination does not disclose all recited parts of these claims.

Second, Applicants note that Causey, III suggests the inclusion of diodes within the lead electrode assembly for the purpose of passive multiplexing of the applied defibrillation signal. Such diodes represent a voltage drop in any circuit system where current is expected to pass. Typically, a diode will have anywhere from 0.3 volts and up as a threshold voltage. For sensing cardiac signals, however, sensed signals prior to amplification rarely exceed 100 millivolts (0.1 volts), even when using near field sensors disposed within the heart. Thus, a diode placed as shown by Causey, III would prevent sensing using the defibrillation shocking electrodes. Hence the primary reference teaches away from the proposed combination.

Claim 193 recites a step of sensing an abnormality in the patient's cardiac rhythm using electrodes disposed internally to the patient but not contacting the patient's heart. For at least the reasons stated above, the cited combination does not fairly disclose or suggest such a step, and further, the combination, and in particular the primary reference, teaches away from such a step. In light of the above, it is believed that claim 193, as well as dependent claims 194 and 196-199 are patentable over Causey, III in view of Yang.

In paragraph 9 of the Office Action, claim 200 was rejected as being unpatentable over Causey, III in view of U.S. Patent No. 5,292,338 to Bardy. U.S. Patent No. 5,895,414 to

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Sanchez, Zambrano is also cited in this rejection. However, claim 200 has been amended to depend from claim 193. It is believed that claim 193 is patentable over the combination of Causey, III, in view of other references due to Causey, III teaching sensing within the heart and due to Causey, III teaching the inclusion of diodes in the shocking electrode lead assemblies. Neither Bardy nor Sanchez, Zambrano, appear to teach sensing without the use of a sensor disposed in the heart. In light thereof, claim 200 is also believed to be in condition for allowance at least for reasons similar to those given for claim 193.

In paragraph 11 of the Office Action, the Examiner stated the allowability of claims 195, 201-206, 208, 209, 211-214, and 216-217.

Reconsideration and reexamination are respectfully requested. It is believed that all pending claims, namely claims 192-206 and 208-217, are now in condition for allowance, and Applicants respectfully request issuance of a Notice of Allowance in due course. If a telephone conference would be of assistance, please contact the undersigned attorney at 612-677-9050.

Respectfully submitted,

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By their Attorney,

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